UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,409	12/30/2003	Johanna Jacoba Maria Meulenberg	01-1793-4-C4	4880

75413 7590 06/19/2009

Michael P. Morris
Boehringer Ingelheim USA Corporation
900 Ridgebury Road
Ridgefield, CT 06877-0368

EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
06/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

Office Action Summary	Application No.	Applicant(s)	
	10/750,409	MEULENBERG ET AL.	
	Examiner	Art Unit	
	MYRON G. HILL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,22,24-26,28,30 and 32-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,22,24-26,28,30 and 32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the papers filed 2/16/09.

This action is on claims 21, 22, 24-26, 28, 30, and 32-37.

Claim Objections

Claim 21 is objected to because of the following informalities: there is an extra comma in line 4. Appropriate correction is required.

Rejections Necessitated By Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 22, 24-26, 28, 30, and 32-37are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that the deposits show more species were disclosed.

Applicant's arguments have been fully considered and not found persuasive.

At least one of the viruses cited by applicant does not contain SEQ ID# 18 at the 5'end. See SEQ ID# 24 which corresponds to the deposit VR-2332.

Applicant asserts that the amended claims provide a genus of PRRSV but these do not to show the genus of PRRSV that have SEQ ID# 18 at the 5' end.

The only species disclosed by Applicant is the sequence of the Leylestad virus. At paragraph 42 of the specification, it is disclosed that SEQ ID# 18 was missing from the published sequence and that that sequence was added to the genome length clone to make it infectious. This fact is disclosed in several other locations in the specification.

None of the references to SEQ ID# 18 refer to it as being added to any genome length sequence. As pointed out above it is only used to make the clone of the invention infectious because it was not in the published sequence.

Claims 26 and 30 recite SEQ ID# 18 "renders" the molecule "infectious" Applicant has not shown that adding the sequence to a genome makes it infectious. As pointed out above, the SEQ ID# 18 was the missing part of the published sequence not some special sequence that renders a clone infectious.

There is also no showing that clones with a ten base extension at the 5' end are intended or infectious.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 22, 24-26, 28, 30, and 32-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims require both SEQ ID# 18 at the 5' end and the sequence of the genome of the deposit. It is not clear what applicant means. Only the CNCM I-1102 deposit contains this at the 5' end. The other viruses do not. VR-2332 virus consists of SEQ ID# 24 included in this CIP. The 5' end is not the 10 nucleotides of SREQ ID# 18.

Claim 26 is not cleat because limitations of the claim from which it depends are removed, "not transfected" and "does not contain". It is not clear what the metes and bounds of the claimed matter is meat to be.

Claims 21, 22, 24- 26, 28, and 30 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the said claims. The specification does not provide a repeatable method for obtaining the specific deposits, and it does not appear to be readily available material. Deposit of virus strains of PRRSV would satisfy the enablement requirements of 35 U.S.C. 112.

The deposits are mentioned in the prior art section of the specification.

The claims now require the specific deposits to obtain the nucleic acid sequence of the recited strains. It is not disclosed in the specification that all the deposits are publicly available.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that **all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent,** would satisfy the deposit requirements. See 37 CFR 1.808.

Priority for 102 Rejections Based on Calvert et al.

While support is noted for the individual words of the claims in this CIP application, it is noted that SEQ ID# 24 is new to this filing. SEQ ID# 24 is the structure/function element of the claim. Thus, claim 32 is only given priority to 12/30/03.

It is noted that the following rejections were made in the action mailed 10/11/06 and applicant's response was to amend the claims and remove the reference to SEQ ID# 24.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 32 is rejected under 35 U.S.C. 102(a) as being anticipated by Calvert *et al.* (US 6500662).

The claims are drawn to SEQ ID# 24 or a sequence that hybridizes to SEQ ID# 24 under stringent conditions. The limitation of SEQ ID# 18 is discussed above.

Calvert *et al*. teach a sequence (SEQ ID# 1) that is 100% identical to the claimed SEQ ID # 24 (see SEQ ID# 1 of the patent).

The claim is interpreted to not include SEQ ID# 18 because it is not clear how a nucleic acid can have two different 5' ends as noted above and that the intent or possession of SEQ ID# 18 at the 5'end of SEQ ID# 24 was not disclosed in the application at the time of filing.

Thus, Calvert *et al*. anticipate the claimed invention.

Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Calvert *et al*. (EP 1018557 A2 pub 12-2000).

The claims are drawn to SEQ ID# 24 or a sequence that hybridizes to SEQ ID# 24 under stringent conditions. The limitation of SEQ ID# 18 is discussed above in the 102(a) rejection..

Calvert *et al*. teach a sequence (SEQ ID# 1) that is 100% identical to the claimed SEQ ID # 24 (see SEQ ID# 1 of the EP document).

Thus, Calvert *et al*. anticipate the claimed invention.

Claim 32 is rejected under 35 U.S.C. 102(e) as being anticipated by Calvert *et al*. (US 6500662).

The claims are drawn to SEQ ID# 24 or a sequence that hybridizes to SEQ ID# 24 under stringent conditions.

Calvert *et al*. teach a sequence (SEQ ID# 1) that is 100% identical to the claimed SEQ ID # 24 (see SEQ ID# 1 of the patent). The limitation of SEQ ID# 18 is discussed above in the 102(a) rejection..

Thus, Calvert *et al*. anticipate the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 25 and 30 are rejected under 35 U.S.C. 102(b) as anticipated by Wensvoort *et al*. (WO 92/21375).

Applicant argues that the reference does not teach SEQ ID# 18 and that the amendment overcomes the rejection.

Applicant's arguments have been fully considered and not found persuasive.

The Wensvoort *et al*. isolate the same virus and the viral genome contained therein is an infectious RNA molecule. The viral genome of Wensvoort *et al*. is full length and thus contains SEQ ID# 18 at the genome end. The virus as the deposit CNCMI-1102 recited in the claims (see claim 1 of WO 92/21375).

Thus, Wensvoort *et al*. clearly anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21, 22, 24-25, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wensvoort *et al*. (WO 92/21375), Moormann *et al*. (Journal of Virology 1996, Vol 70, pages 763-770).

Applicant argues that prior art would not result in the invention because it does not teach SEQ ID# 18 and one would not be able to use the methods of the claimed subject matter without the present invention.

Applicant's arguments have been fully considered and not found persuasive.

Wensvoort *et al*. (WO 92/21375) teaches a viral genome that contains SEQ ID# 18 at the 5' prime end of the genome and is the same virus as the deposit CNCMI-1102 recited in the claims (see claim 1 of WO 92/21375).

Thus, the claims are unpatentable over Wensvoort *et al*. and Moormann *et al*.

Claims 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wensvoort *et al*. (WO 92/21375), and Moormann *et al*. (Journal of Virology 1996, Vol 70, pages 763-770) further in view of Drew et al.

Wensvoort *et al*. and Moormann *et al*. have been discussed previously.

Moormann *et al*. discuss the usefulness of marker vaccines (Abstract, introduction, and Discussion).

Wensvoort *et al*. teach that LA (a strain of PRRSV) can be used a live vector for foreign antigens (paragraph spanning 6-7).

Neither Wensvoort *et al*. nor Moormann *et al*. teach using ORF 7 for modification.

Drew et al. teach antibodies to PRRSV strains and the different reactivity (abstract and figures).

One of ordinary skill in the art at the time of invention would have been motivated to modify ORF7 knowing that antibodies can be used to detect differences between strains. One of ordinary skill in the art at the time of invention would have been motivated to modify the recombinant virus made as discussed above in the 103 rejection based on Wensvoort *et al*. and Moormann *et al*. to be able to identify recombinant virus or identify vaccines used.

Thus, it would have been prima facie obvious to modify the recombinant of Wensvoort *et al*. and Moormann *et al*. as a marker virus with the expectation of success.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MYRON G. HILL whose telephone number is (571)272-0901. The examiner can normally be reached on M-Th and flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

/M. G. H./
Examiner, Art Unit 1648